

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-897V

Filed: July 21, 2023

PUBLISHED

TIMOTHY WOODS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioner.

Mary Eileen Holmes, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

On June 30, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa, *et seq.* (2012),² alleging that, as a result of his October 11, 2014, influenza (“flu”) vaccination, he suffered orbital eye pain, decreased vision, vision loss, and optic neuritis. (ECF No. 1.) Alternatively, petitioner alleged the subject flu vaccination significantly aggravated these conditions. (*Id.*) On December 6, 2022, a Finding of Fact issued, concluding that petitioner did not preponderantly demonstrate that he suffered optic neuritis as alleged. (ECF No. 101, p. 21; see *also Woods v. Sec’y of Health & Human Servs.*, No. 17-897V, 2023 WL 19182, at *16 (Fed. Cl. Spec. Mstr. Dec. 6, 2022).) For the reasons described below, I now further conclude that petitioner is *not* entitled to compensation.

¹ Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa, *et seq.*

I. Procedural History

As noted above, I issued a Finding of Fact as to petitioner's diagnosis on December 6, 2022, finding there is not preponderant evidence petitioner suffered optic neuritis. (ECF No. 101, p. 21; *Woods*, 2023 WL 19182, at *16.) The procedural history leading to the Finding of Fact is discussed in the Finding of Fact itself and need not be repeated herein. (ECF No. 101, pp. 2-4; *Woods*, 2023 WL 19182, at *1–3.)

Because both the petition and petitioner's supporting expert report as to vaccine causation were premised on his alleged optic neuritis, the Finding of Fact was presumptively dispositive based on the case as it had been framed. (ECF No. 101, pp. 21-22; *Woods*, 2023 WL 19182, at *16.) However, petitioner was provided an opportunity to indicate whether he had any other basis upon which to proceed. (ECF No. 102.) Absent that, a dismissal was anticipated. (*Id.*)

Petitioner then filed a motion for review seeking to challenge the Finding of Fact. (ECF No. 104.) However, the Court of Federal Claims dismissed the motion for review, concluding that the Finding of Fact did not constitute a decision under 42 U.S.C. § 300aa–12(d)(3)(A). (ECF No. 112, p. 3.) The Court noted that “[i]f Petitioner so chooses, he may raise his objections to Special Master Horner's Finding of Fact once Special Master Horner has issued a decision within the meaning of the Vaccine Act.” (*Id.*)

After petitioner's motion for review was dismissed, I issued an order instructing petitioner to file either a status report confirming he intends to develop the record regarding an injury other than optic neuritis or a written submission pursuant to Vaccine Rule 8(d). (ECF No. 113.) On July 14, 2023, petitioner filed a status report indicating that “[a]s petitioner's treating providers diagnosed him with optic neuritis, and this diagnosis is supported by both of his experts, petitioner simply cannot file an amended petition for another injury. Petitioner wishes to preserve his right to file a motion for review or motion for reconsideration and therefore asks the Court to issue a decision in accordance with its Finding of Fact issued on December 6, 2022” (ECF No. 114.)

II. Brief Summary of the Record Evidence

The full factual record underlying the Finding of Fact as to diagnosis is contained in the Finding of Fact itself and need not be repeated. (ECF No. 101, pp. 5-15; *Woods*, 2023 WL 19182, at * 3–11.) Very briefly, at about 36 years of age, petitioner received the subject flu vaccination on October 11, 2014. (Ex. 4, p. 1.) About nine months later, he sought care from optometrist Bryan Hoke, O.D., for several symptoms, including headache, eye pain, blurry vision, and decreased color vision. (Ex. 44, pp. 2, 5.) Petitioner had delayed seeking treatment for several reasons, including most notably that he was caring for his wife and taking on additional household burdens due to his wife having recently suffered a stroke. (Ex. 7, p. 2.) Dr. Hoke referred petitioner to the Wolfe Eye Clinic where he saw ophthalmologist LeAnn Larson, M.D., who in turn

recommended a neuro-ophthalmology consult. (Ex. 1, pp. 1-2.) Neither Dr. Hoke nor Dr. Larson diagnosed or recorded any suspicion of optic neuritis.

Petitioner ultimately saw neuro-ophthalmologist Matthew Thurtell, M.D., on November 4, 2015, just over a year after receiving the vaccination at issue. (Ex. 3, pp. 9-15.) Based on the reported history, Dr. Thurtell suspected an attack of optic neuritis that “may have been vaccination-related,” but as of the time of his examination could only objectively confirm mild optic neuropathy.³ (*Id.* at 14.) Dr. Thurtell recommended a follow up MRI for further evaluation of demyelinating disease, which petitioner did not pursue. (*Id.*)

Based on petitioner’s report of a prior episode of optic neuritis following vaccination, petitioner’s primary care provider, Dr. Vernon, subsequently agreed that it was reasonable for petitioner to request an exemption from future flu vaccinations. (Ex. 2, p. 4.) However, Dr. Vernon did not opine that petitioner’s condition was vaccine-caused, noting instead that there are other factors that could have contributed to optic neuritis. (*See id.*)

The parties filed competing expert opinions with respect to the accuracy of petitioner’s alleged optic neuritis diagnosis. Marc A. Bouffard, M.D., offered an extensive expert neuro-ophthalmology opinion on respondent’s behalf indicating that petitioner’s history is not consistent with optic neuritis and that there is inadequate evidence available to support the diagnosis of optic neuritis. (Exs. A-B, G, J, L.⁴) Todd A. Lefkowitz, M.D., offered a much briefer expert ophthalmology opinion on petitioner’s behalf disagreeing with aspects of Dr. Bouffard’s assessment and endorsing the optic neuritis diagnosis. (Exs. 40-41.)

Two additional expert opinions were filed in this case. Petitioner filed an expert opinion by neuroimmunologist Lawrence Steinman, M.D. Dr. Steinman opined as to vaccine-causation, but not diagnosis. (Exs. 8-9, 36.) He indicated that he deferred to Dr. Thurtell’s diagnosis. (Exs. 8, p. 6; 36, p. 1.) Dr. Steinman opined that the condition of optic neuritis can be caused by the flu vaccine. Specifically, he opined that “[p]etitioner’s theory” is that “[t]here is molecular mimicry between components of the 2014-2015 influenza vaccine and the myelin molecule known as MOG. An immune attac[k] against MOG occurs in optic neuritis.” (Ex. 8, p. 8.) Absent a diagnosis of optic

³ To be clear, optic neuritis was listed as a diagnosis for this encounter. (Ex. 3, p. 13.) However, the more detailed narrative assessment indicates, “Not surprisingly, today’s neuro-ophthalmic evaluation showed findings consistent with a mild optic neuropathy OS. Based on the history, I suspect he had an attack of optic neuritis OS. The attack began shortly after a flu vaccine and, thus, the attack may have been vaccination-related.” (*Id.* at 14.) Accordingly, the Finding of Fact explained that in a prior order I had advised the parties that in my view it would not be accurate to conclude that the diagnosis of optic neuritis was not made, but the fact of the diagnosis does not mean the basis for the diagnosis is beyond challenge. (ECF No. 101, p. 2; *see also Woods*, 2023 WL 19182, at *1.) Thus, this is how Dr. Thurtell’s opinion was addressed by the Finding of Fact. (ECF No. 101, p. 21; *see also Woods*, 2023 WL 19182, at *15-16.)

⁴ An additional report marked as Exhibit M was filed but was not considered for reasons discussed within the Finding of Fact. (ECF No. 101, p. 17-19; *see also Woods*, 2023 WL 19182, at *13-14.)

neuritis, Dr. Steinman did not otherwise opine that petitioner's condition could be considered vaccine caused. Dr. Steinman opined there is a logical sequence of cause and effect between petitioner's vaccination and his injury because "[t]he influenza vaccine contains components that have structural homologies with MOG. Immunity to MOG is associated with optic neuritis." (*Id.* at 20.) Respondent filed a competing expert opinion by immunologist J. Lindsay Whitton, M.D., Ph.D. (Exs. C-D, H.) Dr. Whitton's opinion challenged Dr. Steinman's assessment that the flu vaccine can cause optic neuritis. (Ex. C, pp. 4-15.)

III. Discussion

In light of all of the above, this case is now ripe for resolution. Petitioner has specifically requested that a decision be issued on the current record in accordance with the prior Finding of Fact. (ECF No. 114.) I have also concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case based on the existing record. See *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993); see also Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

The Vaccine Act prohibits a special master from ruling for petitioner based solely on his allegations unsubstantiated by medical records or medical opinion. See 42 U.S.C. § 300aa–13(a)(1). Generally, to receive compensation in the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to a covered vaccine, or (2) that he suffered an injury that was actually caused by a covered vaccine. See 42 U.S.C. § 300aa–13(a)(1)(A); 42 U.S.C. § 300aa–11(c)(1). To satisfy the burden of proving causation in fact, petitioner must meet the so-called "*Althen* test" by demonstrating by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

However, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1351–53 (Fed. Cir. 2011). Importantly, "the function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). Petitioner must "specify his vaccine-related injury and shoulder the burden of proof on causation." *Broekelschen v. Sec'y of*

Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). “Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for ‘vaccine-related injury or death.’” *Stillwell v. Sec’y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014) (emphasis omitted) (quoting 42 U.S.C. § 300aa–11(c)). And, in any event, a petitioner must prove by a preponderance of the evidence the factual circumstances surrounding his claim. See 42 U.S.C. § 300aa–13(a)(1)(A).

In this case, petitioner has not demonstrated by preponderant evidence that he suffered optic neuritis following administration of his October 11, 2014 flu vaccination for all the reasons discussed in my prior December 6, 2022 Finding of Fact. (ECF No. 101; *Woods*, 2023 WL 19182.) However, petitioner’s expert on causation, Dr. Steinman, formulated his causal opinion based on the assumption that petitioner suffered optic neuritis and his explanation that the flu vaccine can cause optic neuritis via molecular mimicry between vaccine components and myelin tissue molecules known to be attacked in the context of optic neuritis. Absent optic neuritis, Dr. Steinman did not provide any opinion that could otherwise implicate petitioner’s flu vaccine as a cause of any of his symptoms.

Any causal assessments contained in petitioner’s medical records were likewise premised on the presence of optic neuritis. Petitioner’s treating neuro-ophthalmologist, Dr. Thurtell, opined that petitioner’s post-vaccination symptoms “may have been vaccination-related” because he suspected an attack of optic neuritis arising shortly after vaccination. (Ex. 3, p. 14.) In that regard, he recommended further MRI follow up to screen for demyelinating disease. (*Id.*) A demyelinating optic neuritis would dovetail with Dr. Steinman’s theory that components of petitioner’s vaccination cross-reacted with myelin tissue. (Indeed, Dr. Steinman explicitly relied on Dr. Thurtell’s diagnosis of optic neuritis.) However, the same cannot be said of the optic neuropathy that Dr. Thurtell actually observed upon examination, which would not necessarily have the same etiology. See, e.g., *Robertson v. Sec’y of Health & Human Servs.*, No. 18-554V, 2022 WL 17484980, at *12–13 (Fed. Cl. Spec. Mstr. Dec. 7, 2022) (finding that the expert’s discussion of demyelinating optic neuritis was irrelevant where petitioner suffered an ischemic form of optic neuropathy); see also *Katz v. Sec’y of Health & Human Servs.*, No. 04-714V, 2005 WL 6117659, at *18 (Fed. Cl. Spec. Mstr. Nov. 30, 2005) (finding that petitioner’s expert’s theory was “mismatched” to petitioner’s diagnosis where petitioner suffered a non-demyelinating form of optic neuritis). Apart from referencing a suspected attack of optic neuritis, Dr. Thurtell did not otherwise suggest that any of petitioner’s symptoms were caused by his vaccination.

For all these reasons, a separate *Althen* analysis relative to optic neuritis is not required given the prior Finding of Fact. Petitioner necessarily has not met his burden of proof with respect to causation-in-fact. See *Lombardi*, 656 F.3d at 1352–53; *Broekelschen*, 618 F.3d at 1345–46; *Stillwell*, 118 Fed. Cl. at 56. Petitioner was provided an opportunity to determine whether he could demonstrate his symptoms to be vaccine caused without relying on a diagnosis of optic neuritis, but he has indicated that he cannot do so. (ECF No. 114.)

IV. Conclusion

Nothing in this decision is intended to diminish the fact that petitioner did experience a concerning optic condition of some kind and that this occurred during what was clearly already a stressful period in his life. For that he has my sympathy. Moreover, given all of the above, it is understandable that he would come to personally believe that his condition was caused by his flu vaccination. However, for all the reasons discussed herein, petitioner has not preponderantly demonstrated that he actually suffered a vaccine-caused injury and is therefore not entitled to compensation. Accordingly, this case is **DISMISSED**.⁵

IT IS SO ORDERED.

s/Daniel T. Horner

Daniel T. Horner
Special Master

⁵ In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.